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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,398	07/03/2001	James Scott Hutchison	A1713	3468
33197	7590	04/28/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			GRUN, JAMES LESLIE	
4 VENTURE, SUITE 300			ART UNIT	PAPER NUMBER
IRVINE, CA 92618			1641	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/898,398	Applicant(s) HUTCHISON, JAMES SCOTT	
	Examiner James L Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-80 and 82 is/are rejected.
- 7) ☒ Claim(s) 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 12 February 2004 is acknowledged and has been entered. Claims 62-82 are newly added. Claims 1-61 have been cancelled. Claims 62-82 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 75 and 82 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 75 does not appear to further limit the subject matter of claim 74, rather a claim to a kit is broader than a claimed isolated antibody.

Claim 82 does not appear to further limit the subject matter of claim 74 because amino acid 1 is already included.

Claims 74-76, 79, 80, and 82 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kuronen et al. (Eur J. Clin Chem Clin Biochem 35(6): 435, 1997) for reasons of record in the prior rejection of the similar subject matter of claims 27, 29, 30, 32-35, 37, 38, 40, 42-47, 49, 50, 52-55, 58, and 60.

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Claims 74-77, 79, 80, and 82 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brown et al. (J. Immunol. Meth. 109: 139, 1988) for reasons of record in the prior rejection of the similar subject matter of claims 27, 29, 30, 32-35, 37, 38, 40, 42-47, 49-55, and 60.

Claims 62-64, 66-72, 74-76, 78-80, and 82 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuronen et al. (Eur J. Clin Chem Clin Biochem 35(6): 435, 1997) in view of Gao et al. (J. Bone Min. Res. 14(Suppl. 1):S446, Abstract SU057, 1999) and John et al. (J. Clin Endo Metab. 84: 4287, 1999) for reasons of record in the prior rejection of the similar subject matter of claims 23-35, 37-50, 52-55, 58, 60, and 61.

Claims 65, 73, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuronen et al. in view of Gao et al. (1999) and John et al. as applied to claims 62-64, 66-72, 74-76, 78-80, and 82 above, and further in view of Gao et al. (Clinica Chim. Acta 245: 39, 1996) for reasons of record in the prior rejection of the similar subject matter of claims 51, 56, and 57.

Applicant's arguments filed 12 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the prior art of record, taken alone or in combination, do not disclose, teach, or suggest antibodies as instantly claimed specific for a "three-dimensional" epitope including or consisting of amino acid residues 1-13 of SEQ ID NO:1, particularly antibodies as disclosed specific for an epitope which is argued as being non-linear, conformational, and requiring of residues in both regions 1-6 and 7-13 for binding. This is not found persuasive for the reasons of record regarding the specificities of the antibodies of

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the prior art which bind to epitopes within the recited region. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a non-linear conformational epitope which requires residues in both regions 1-6 and 7-13 for antibody binding) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is suggested that recitation of a "three-dimensional" epitope neither explicitly or implicitly limits antibody specificity to a non-linear conformational epitope consisting of residues 1-13 as would appear applicant's intent and argument.

Claim 81 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.



James L. Grun, Ph.D.
April 27, 2004



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1898/641